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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,416	02/22/2002	Oliver Yoa-Pu Hu	39297-174170	8467
26694	7590	06/30/2004	EXAMINER	
VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP			KIM, VICKIE Y	
P.O. BOX 34385			ART UNIT	
WASHINGTON, DC 20043-9998			PAPER NUMBER	

1614

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/14

Office Action Summary

Application No.

10/079,416

Applicant(s)

YOA-PU HU ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16 and 33-47 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 and 33-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 43-47 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

RCE acknowledged

A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Status of Application

1. Acknowledgement is made of amendment filed September 04, 2003. Upon entering the amendment, claims 1-9 and 17-32 are canceled.
New claims 33-47 are added.
2. The claims 10-16 and 33-47 are pending.
3. The claims 10-16 were previously withdrawn from consideration as being a non-elected invention.
4. The newly added claims 33-47 are subjected to restriction requirement.
 - a. Group I, claims 33-42, drawn to a method of prolonging a therapeutic effect of a dermatological drug in a mammal using a topical administration of a dermal cytochrome P450 1A(CYP1A, hereafter) inhibitor.
 - b. Group II, claims 43-47, drawn to a pharmaceutical composition comprising a free base or a pharmaceutically acceptable salt of said dermal CYP1A inhibitor and a carrier.

The group II , claims 43-47 are considered to be elected invention(same invention elected during the previous prosecution) and the group II invention will be presented for the examination and the group I, claims 33-42 will be withdrawn from the consideration.

Applicant is informed that the office is not to permit the applicant to shift to claiming another invention after an election is once made and action given on the elected subject matter, Note that the applicant cannot, as a matter of right, file a request for continued examination(RCE) to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined(i.e. applicant cannot switch inventions by way of an RCE as a matter of right), see MPEP 819.

If applicant wishes to pursue independent invention from the invention previously elected and examined, applicant must file divisional or CIP to request for the examination of such invention.

Claim Objections

5. Claims 44-45 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The claims 44-45 are drawn to a composition comprising a dermal CYP1A inhibitor and a carrier, that is dependent on claim 43(a pharmaceutical composition). The further limitation recited in the claims 44-45 is related to the use of said pharmaceutical composition of claim 43, rather than further limiting the characteristics or features of the

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composition of claim 43, that affects the structure of the said composition of claim 43(scope of the claimed subject matter). For instance, the claims 44-45 are directed to how the composition of claim 43 is administered by or with.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Thus, the claims 44-45 are treated same as previous claim since the scope of the subject matter has not been changed and examined with only to the extent that they read on the scope of claimed subject matter of a previous claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Eini et al(US5227163).

Claims are drawn to a composition comprising a dermal CYP1A inhibitor such as terpineol in the amount of about 10% by weight and a carrier.

Eini et al(US'163, hereafter) teaches a composition comprising terpenoid-alcohols(terpene-ols) such as terpineol in a concentration of between 0.01-50%,preferably 0.01-10%, by weight and a pharmaceutically and/or cosmetically effective carrier. It is noted that terpineol is a CYP1A inhibitor(self evidenced by claims 44) and thus the recitation required by the claim 43(i.e. CYP1A inhibitor) is inherently

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met. The claims 45-46 are properly included in this rejection because of reason set forth above in claim objection. The claimed subject matter of the claims 45-46 are met by the cited reference.

All the critical elements required by the instant claims are well taught and all the claims 43-47 are anticipated by the cited reference.

Conclusion

7. Few references are cited because they are particularly pertinent to the claimed subject matter as following:

- a. Gans et al(US2003/0040504A1), see abstract and claims.
- b. Ikuo et al(JP 10-114648, English translated version is provided), see abstract and claims.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**VICKIE KIM
PRIMARY EXAMINER**

Vickie Kim
June 24, 2004
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